



# **ISO 9000**

## **Lesson 3 ISO 9000 Quality System Elements (ISO 9001)**

**Prepared for NASA  
by OPM and BDM Federal, Inc.**

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## 20 Quality System Elements



- **Management Responsibility**
- **Quality System**
- **Contract Review**
- **Design Control**
- **Document and Data Control**
- **Purchasing**
- **Control of Customer-supplied Product**
- **Product Identification and Traceability**
- **Process Control**
- **Inspection and Testing**
- **Control of Inspection, Measuring, and Test Equipment**
- **Inspection and Test Status**
- **Control of Non-conforming Product**
- **Corrective and Preventive Action**
- **Handling, Storage, Packaging, Preservation, and Delivery**
- **Control of Quality Records**
- **Internal Quality Audits**
- **Training**
- **Servicing**
- **Statistical Techniques**



# Obtaining Copies of ISO Standards

- **Since this training is not a substitute for the actual ISO Standards, official copies of relevant documents should be obtained.**
- **Documents are protected by copyright.**
- **Documents may be obtained from ANSI or ASQ.**
- **Copies of the following documents should be obtained:**
  - **ISO 9001 (or Equivalent ANSI/ Q Series)**
  - **ISO 9000-1**
  - **ISO 9004-1**
  - **ISO 8402**
  - **ISO 10011-1**
  - **ISO 10011-2**
  - **ISO 10011-3**



# ISO 9001: ANSI/ASQ Q9001

- **Understanding 9001 is tantamount to understanding 9002 and 9003.**
- **Quality system elements are complementary to, not a substitute for, technical requirements.**
- **Elements may be tailored when necessary.**
- **ISO 9001 should be used when a supplier's capability to meet requirements must be demonstrated.**



# **Description and Discussion of 20 Q9001 Quality System Elements**

## **20 Q9001 Quality System Elements**

# **Management Responsibility**



- **4.1 Management Responsibility Defines Those Parts of a Quality System That Only Management has the Authority to Implement.**
  - **4.1.1 Quality Policy**
  - **4.1.2 Organization**
    - **Responsibility**
    - **Resources**
    - **Management Representative**
  - **4.1.3 Management Review**

## **20 Q9001 Quality System Elements**

# **Quality System**



- **4.2 Quality System**  
**Addresses the Overall Quality System Structure and Content Needed to Deploy Executive Management's Quality Policy and Management's Delegated Authority and Responsibility for Work Affecting Quality.**
  - **4.2.1 General**
    - **Quality Manual**
  - **4.2.2 Quality System Procedures**
  - **4.2.3 Quality Planning**

## **20 Q9001 Quality System Elements**

# **Contract Review**



- **4.3 Contract Review**  
**Specifies the Necessary Elements in an Enterprise's Process for Establishing/ Reviewing Requirements in Outgoing Proposals and Incoming Orders.**
  - **4.3.1 General**
    - **Documentation**
  - **4.3.2 Review**
  - **4.3.3 Amendment to a Contract**
  - **4.3.4 Records**



## **20 Q9001 Quality System Elements**

# **Design Control**



- **4.4 Design Control**  
**Defines the Major Elements that Each Enterprise's Design and Development Process Must Address.**
  - **4.4.1 General**
    - **Documentation**
  - **4.4.2 Design and Development Planning**
  - **4.4.3 Organization and Technical Interfaces**
  - **4.4.4 Design Input**
  - **4.4.5 Design Output**
  - **4.4.6 Design Review**
  - **4.4.7 Design Verification**
  - **4.4.8 Design Validation**
  - **4.4.9 Design Changes**



## 20 Q9001 Quality System Elements

# 4.4 Design Control System

### 4.4 Design Control System

**Establish and maintain procedures for controlling and verifying that the design efforts result in meeting the specified requirements.**

4.4.2 Plan design project

4.4.3 Establish communication/information flow necessary to carry out design

4.4.4 Identify design input requirements

4.4.5 Develop and document design output to meet input

4.4.6 Review design results

4.4.7 Verify design

4.4.8 Validate product

4.4.9 Review and approve all design changes

Keep records of required design activities (4.16)



## **20 Q9001 Quality System Elements**

# **Document and Data Control**



- **4.5 Document and Data**  
**Defines the Requirements for Controlling Documents and Data Associated with the Operation of the Enterprise's Quality Management System.**
  - **4.5.1 General**
    - **Documented Procedures**
  - **4.5.2 Document and Data Approval and Issue**
  - **4.5.3 Document and Data Changes**

# 20 Q9001 Quality System Elements

## 4.5 Document Control System



### 4.5 Document Control System

**4.5.1 Documented procedures are established and maintained to control documents and data**

New documents are written



**4.5.2 Authorized personnel review and approve before issue**

**4.5.2 A master control list is established and maintained**

A screenshot of a spreadsheet application showing a master control list. The spreadsheet has multiple columns with headers such as "ID", "Title", "Version", "Status", "Date", and "Author". It contains numerous rows of data, each representing a document or data item, with some cells highlighted in yellow.

New and revised documents are made available at point of use. Obsolete copies are removed.

Documents may be in any form - paper hardcopy or electronic media

# 20 Q9001 Quality System Elements

## Purchasing



- **4.6 Purchasing**  
**Defines the Quality Related Requirements for each Enterprise's Procurement Processes.**
  - **4.6.1 General**
    - **Documented Procedures**
  - **4.6.2 Evaluation of Subcontractors**
  - **4.6.3 Purchasing Data**
  - **4.6.4 Verification of Purchased Product**

## **20 Q9001 Quality System Elements**

### **Control of Customer-supplied Product and Product Identification and Traceability**



- **4.7 Control of Customer-supplied Product  
Defines the Requirements for the Management  
of Customer-furnished Articles.**
- **4.8 Product Identification and Traceability  
Defines the Requirements for Product  
Identification and for Unit or Batch Traceability.**

## **20 Q9001 Quality System Elements**

# **Process Control**



- **4.9 Process Control**  
**Defines the Requirements for the Control of Production, Installation, and Servicing Processes that Affect Quality.**
  - **Documented Procedures**
  - **Suitable Equipment**
  - **Compliance with Reference Standards, Plans, Procedures**
  - **Monitoring of Process Parameters**
  - **Approval of Processes and Equipment**
  - **Suitable Maintenance**
  - **Special Processes**

## **20 Q9001 Quality System Elements**

# **Inspection and Testing**



- **4.10 Inspection and Testing**  
**Defines the requirements for Conducting Inspections and Tests to Verify that Specific Product Requirements Have Been Met.**
  - **4.10.1 General**
    - **Documented Procedures**
  - **4.10.2 Receiving Inspection and Testing**
  - **4.10.3 In-process Inspection and Testing**
  - **4.10.4 Final Inspection and Testing**
  - **4.10.5 Inspection and Test Records**



## **20 Q9001 Quality System Elements**

### **Control of Inspection, Measuring, and Test Equipment**



- **4.11 Control of Inspection, Measuring, and Test Equipment**  
**Defines the Requirements Each Enterprise Must Address for the Selection, Control, Calibration, and Maintenance of Inspection, Measurement, and Test Equipment.**
  - **4.11.1 General**
    - **Documented Procedures**
    - **Measurement Uncertainty Must Be Known**
  - **4.11.2 Control Procedure**

## ***20 Q9001 Quality System Elements***

# **Inspection and Test Status**

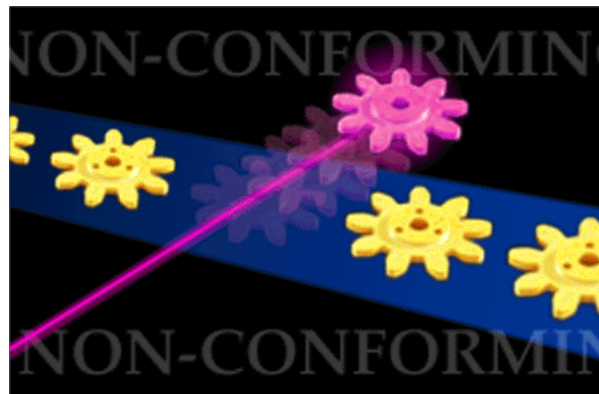


- **4.12 Inspection and Test Status**  
**Defines the Requirements an Enterprise**  
**Must Address to Adequately Identify**  
**Each Product's Inspection and Test**  
**Acceptance or Rejection Status.**

# **Control of Non-conforming Product**



- **4.13 Control of Non-conforming Product**  
**Defines the Requirements each Enterprise Must Address to Adequately Control Non-conforming Products.**
  - **4.13.1 General**
    - **Documented Procedures for Identification, Documentation, Evaluation, Segregation, Disposition, Notification**
  - **4.13.2 Review and Disposition of Non-conforming Product**



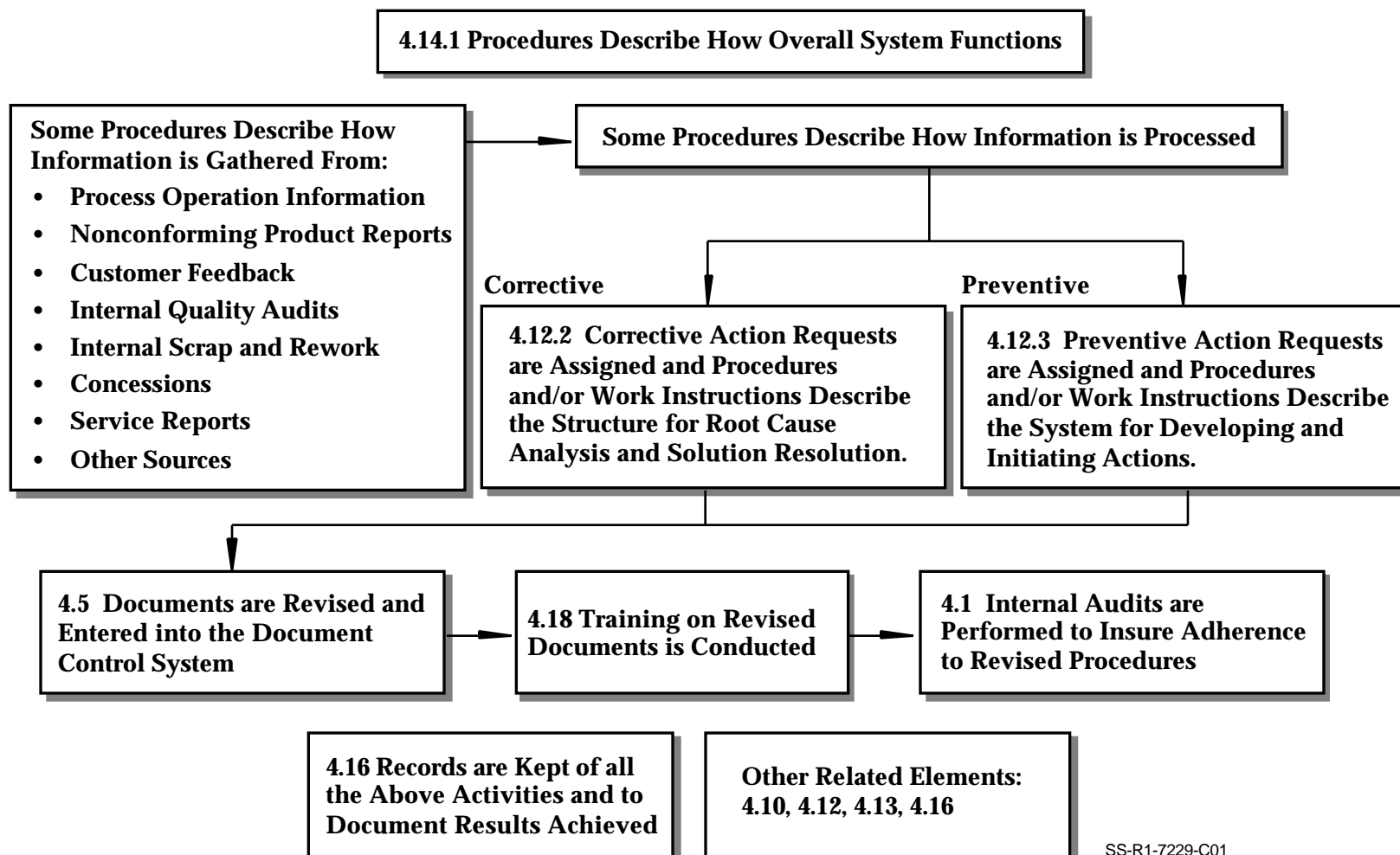


- **4.14 Corrective and Preventive Action**  
**Specifies the Major Elements that Must Be Present in Each Enterprise's Processes for Corrective Action and for Preventive Action.**
  - **4.14.1 General**
    - **Documented Procedures**
    - **Implement and Record any Changes to Documented Procedures Resulting from Corrective/Preventive Action**
  - **4.14.2 Corrective Action**
  - **4.14.3 Preventive Action**



## 20 Q9001 Quality System Elements

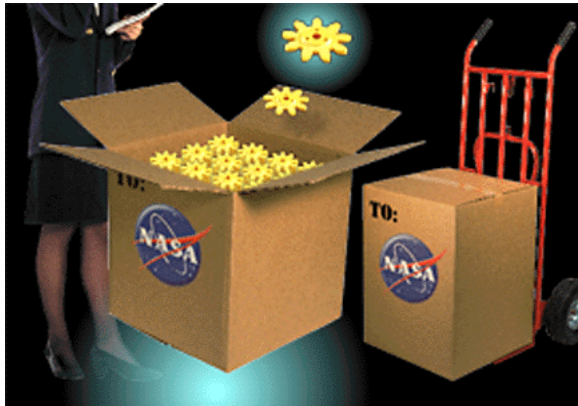
# 4.14 Corrective and Preventive Action



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- **4.15 Handling, Storage, Packaging, Preservation, and Delivery**  
Specifies the Requirements that Each Enterprise's Processes for Product Handling, Storage, Packaging, Preservation, and Delivery Must Meet.



- **4.15.1 General**
  - Documented Procedures
- **4.15.2 Handling**
- **4.15.3 Storage**
- **4.15.4 Packaging**
- **4.15.5 Preservation**
- **4.15.6 Delivery**

## ***20 Q9001 Quality System Elements***

# **Control of Quality Records**



- **4.16 Control of Quality Records**  
**Defines the Requirements for**  
**Management of Quality Records.**

## ***20 Q9001 Quality System Elements***

# **Internal Quality Audits**



- **4.17 Internal Quality Audits**  
**Defines the Requirements for Each Enterprise's Internal Quality Audit Process.**



# 20 Q9001 Quality System Elements

## Internal Audit System

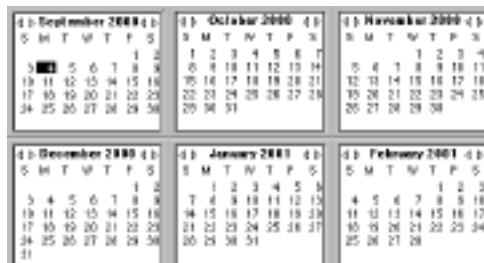


### 4.17 Internal Audit System

**Formal structure for establishment and maintenance of an internal auditing system.**

Verify the existence of documentation to comply with all twenty quality system requirements (that apply) (4.2 & 4.5)

Verify that procedures and work instructions are being followed (4.9)



**Plan and schedule audits based on status and importance of activities to be audited.**

**Audit findings are recorded and forwarded to the affected management.**



**Appropriate corrective action is identified, implemented, and verified.**

# **20 Q9001 Quality System Elements Training**



- **4.18 Training**  
**Defines the Requirements for  
Managing the Identification and  
Delivery of Necessary Training.**

## ***20 Q9001 Quality System Elements*** **Servicing**



- **4.19 Servicing**  
**Defines the Requirements for**  
**Managing Servicing Activities.**

## ***20 Q9001 Quality System Elements***

# **Statistical Techniques**



- **4.20 Statistical Techniques**  
**Defines the Requirements for Identification and Application of Appropriate Statistical Techniques to the Enterprise's Processes and Products.**
  - **4.20.1 Identification of Need**
  - **4.20.2 Procedures**